

Amendments to the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1. (original) A self-contained device for painless, inter-muscular injection of a liquid medicament, comprising:
 - a) a housing having a base for attachment to the skin of a patient,
 - b) an injection needle disposed substantially perpendicular to the base and within the housing, the needle having an injection end, and configured for axial movement between a first position wherein the injection end is within the housing and a second position wherein the injection end extends outwardly from the base to a distance sufficient for intramuscular insertion thereof, the injection needle having an outside diameter greater than 0.20 mm and less than about 0.38 mm,
 - c) a reservoir containing a liquid medicament,
 - d) a means for liquid communication between the reservoir and the injection needle,
 - e) a means for inserting the injection needle to its second position, and
 - f) a means for pumping the medicament from the reservoir to the injection end of the needle.
2. (previously presented) The device according to claim 1 further comprising a means for retracting the injection needle from its second position to a third position within the housing.
3. (original) The device according to claim 1 wherein the insertion distance from the base is at least 5 mm.
4. (original) The device according to claim 2 wherein the inserting means, the pumping means, and the retracting means are configured for automatically and sequentially:
 - a. extending the needle from its first position within the housing to its second position into the patient;
 - b. injecting the medicine via the needle into the patient; and

c. retracting the needle from its second position in the patient to a third position within the housing.

5. (previously presented) A self-contained device for painless, inter-muscular injection of a liquid medicament, comprising:

- a) a housing having a base for attachment to the skin of a patient,
- b) an injection needle disposed substantially perpendicular to the base and within the housing, the needle having an outside diameter less than about 0.38 mm, an inlet end and an opposed injection end, and configured for axial movement between a first position wherein the injection end is within the housing and a second position wherein the injection end extends outwardly from the base to a distance sufficient for intramuscular insertion thereof,
- c) a reservoir containing a liquid medicament, disposed within the housing along a line extending axially from the inlet end of the injection needle,
- d) a means for inserting the injection needle to its second position, and
- e) a reservoir urging means for moving the reservoir into liquid communication with the inlet end of the injection needle, and
- g) a means for retracting the injection needle from its second position to a third position within the housing.

6. (canceled)

7. (previously presented) The device according to claim 5 wherein the injection needle has an outside diameter greater than 0.20 mm.

8. (original) The device according to claim 5 where the inserting means is selected from the group consisting of a mechanical means, a pneumatic means, an electronic means, and an electro-mechanical means, and the reservoir urging means is selected from the group consisting of a mechanical means, a pneumatic means, an electronic means, and an electro-mechanical means.

9. (original) A self-contained device for painless, inter-muscular injection of a liquid medicament, comprising:

- a) a housing having a base for attachment to the skin of a patient,
- b) an injection needle disposed substantially perpendicular to the base and within the housing, the needle having an outside diameter less than about 0.38 mm, inlet end and an opposed injection end, and being configured for axial movement between a first position wherein the injection end is within the housing and a second position wherein the injection end extends outwardly from the base,
- c) a reservoir containing a liquid medicament,
- d) a means for liquid communication between the reservoir and the injection needle,
- e) a means for inserting the injection needle to its second position,
- f) a means for pumping the medicament from the reservoir to the injection end of the injection needle at a substantially constant volumetric flow rate of from about 0.5 μ L/s to about 20 μ L/s.

10. (original) The device according to claim 9 wherein the volumetric flow rate is from about 1 μ L/s to about 4 μ L/s.

11. (original) The device according to claim 9 wherein the means for pumping the medicament is selected from the group consisting of a mechanical pumping means, a pneumatic pumping means, an electronic means, and an electro-mechanical pumping means.

12. (withdrawn) The device according to claim 9 further comprising a means for pre-selecting the depth of insertion of the injection needle at its second position.

13. (previously presented) The device according to claim 9 further comprising a means for retracting the injection needle from its second position to a third position within the housing.

14. (original) A self-contained device for painless, inter-muscular injection of a liquid medicament, comprising:

- a) a housing having a base for attachment to the skin of a patient,

b) an injection needle disposed within the housing, the needle having an outside diameter greater than 0.20 mm and less than about 0.32 mm, having an inlet end and an opposed injection end, and being configured for movement between a first position wherein the injection end is within the housing and a second position wherein the injection end extends through the base,

- c) a reservoir containing a liquid medicament,
- d) a means for liquid communication between the reservoir and the injection needle,
- e) a means for inserting the injection needle to its second position,
- f) a means for pumping the medicament from the reservoir to the injection end of the injection needle at a substantially constant volumetric flow rate of from about 0.5 μ L/s to about 20 μ L/s.

15. (original) The device according to claim 14 wherein the volumetric flow rate is from about 1 μ L/s to about 4 μ L/s.

16. (original) The device according to claim 14 wherein the means for pumping the medicament is selected from the group consisting of a mechanical pumping means, a pneumatic pumping means, an electronic means, and an electro-mechanical pumping means.

17. (original) The device according to claim 14 wherein the injection needle disposed in its first position substantially perpendicular to the base.

18. (withdrawn) The device according to claim 14 further comprising a means for pre-selecting the depth of extension of the injection needle at its second position.

19. (currently amended) A self-contained device for painless, inter-muscular injection of a liquid medicament, comprising:

- a) a housing having a base for attachment to the skin of a patient,
- b) an injection needle disposed substantially perpendicular to the base and within the housing, the needle having an outside diameter less than about 0.038 mm, inlet end and an opposed injection end, and being configured for axial movement between a first position wherein

the injection end is within the housing and a second position wherein the injection end extends outwardly from the base,

c) a reservoir containing a liquid medicament,

d) a means for liquid communication between the reservoir and the injection needle,

e) a means for inserting the injection needle to its second position,

f) a means for pumping the medicament from the reservoir to the injection end of the injection needle at a substantially constant volumetric flow rate of from about 1[[0.5]] μ L/s to about 4[[20]] μ L/s.

20. (canceled)

21. (original) The device according to claim 19 wherein the means for pumping the medicament is selected from the group consisting of a mechanical pumping means, a pneumatic pumping means, an electronic means, and an electro-mechanical pumping means.

22. (original) The device according to claim 5 wherein the injection needle has having an outside diameter greater than 0.20 mm and less than about 0.38 mm.

23. (withdrawn) The device according to claim 14 further comprising a means for pre-selecting the depth of extension of the injection needle at its second position.

24. (withdrawn) A self-contained device for painless injection of a liquid medicament, comprising:

a) a housing having a base for attachment to the skin of a patient, ,

b) an injection needle disposed substantially perpendicular to the base and within the housing, the needle having an injection end, and configured for axial movement between a first position wherein the injection end is within the housing and a second position wherein the injection end extends outwardly from the base, the injection needle having an outside diameter greater than 0.20 mm and less than about 0.38 mm,

c) a reservoir containing a liquid medicament,

d) a means for liquid communication between the reservoir and the injection needle,

e) a means for pre-selecting the depth of extension of the injection needle at its second position,

f) a means for inserting the injection needle to its second position, and

g) a means for pumping the medicament from the reservoir to the injection end of the needle.

25. (withdrawn) The device according to claim 24 further comprising a means for retracting the injection needle between its second position and a third position within the housing.

26. (withdrawn) The device according to claim 24 wherein the distance from the base is at least 0.5 mm.

27. (withdrawn) The device according to claim 25 wherein the inserting means, the pumping means, and the retracting means are configured for automatically and sequentially:

a. extending the needle from its first position within the housing to its second position into the patient;

b. injecting the medicine via the needle into the patient; and

c. retracting the needle from its second position in the patient to a third position within the housing.

28. (previously presented) A self-contained, automatically-sequencing device for painless, inter-muscular injection of a liquid medicament, comprising:

a) a housing having a base for attachment to the skin of a patient,

b) an injection needle disposed within the housing, the needle having an outside diameter less than about 0.38 mm, an inlet end and an opposed injection end, and being configured for movement between a first position wherein the injection end is within the housing and a second position wherein the injection end extends the base to a distance sufficient for intramuscular insertion thereof,

c) a reservoir containing a liquid medicament,

d) a means for liquid communication between the reservoir and the injection needle,

e) a means for inserting the injection needle to its second position,

- f) a means for pumping the medicament from the reservoir to the injection end of the needle,
- g) a means for retracting the injection needle from its second position to a third position within the housing, and
- h) a means for automatically sequencing and activating the inserting means, the pumping means and the retracting means.

29. (original) The automatically-sequencing device according to claim 28 wherein the pumping means pumps the medicament at a substantially constant volumetric flow rate of from about 0.5 $\mu\text{L/s}$ to about 20 $\mu\text{L/s}$.

30. (original) The automatically-sequencing device according to claim 28 wherein the inserting means and the retracting means, independently, are selected from the group consisting of a mechanical means, a pneumatic means, an electronic means, and an electro-mechanical means.

31. (withdrawn) A self-contained device for injecting a medicament, comprising:

- a) a housing having a base for attachment to the skin of a patient,
- b) an injection needle disposed within the housing and having an injection end configured for insertion into the skin of the patient,
- c) a reservoir containing a liquid medicament and configured for liquid communication with the injection needle,
- d) a bandage releasably affixed to the base of the housing, comprising a base-contacting surface and a skin-contacting surface that comprises an affixment for attachment of the device to the skin.

32 (withdrawn) The device according to claim 30 wherein the attachment of the affixment to the skin is greater than the affixment of the bandage to the base, whereby when the attached device is removed from the skin, the bandage detaches from the base of the device and remains attached to the skin.

33. (withdrawn) The device according to claim 32 wherein the affixment of the bandage to the device comprises a first adhesive, and the affixment of the bandage to the skin comprises a second adhesive.
34. (withdrawn) The device according to claim 30 wherein the bandage comprises a pad portion through which the injection needle penetrates when moving between its first and second positions.
35. (withdrawn) The device according to claim 34 wherein the pad comprises a second medicament.
36. (original) The device according to claim 30 wherein the second adhesive comprises a medicament.
37. (withdrawn) The device according to claim 30 further comprising a release layer that overlies the adhesive on the skin-contacting surface of the bandage prior to attachment of the device to the skin.
38. (withdrawn) A method of administering a liquid medicament in an inter-muscular injection painlessly to a patient, comprising the steps of:
 - a) inserting the injection tip of an injection needle through the skin and into the muscle of a patient, the needle having an outside diameter greater than 0.20 mm and less than about 0.38 mm, and
 - b) injecting the liquid medicament through the needle and into the patient at a substantially constant volumetric flow rate of from about 0.05 μ L/s to about 50 μ L/s.
39. (withdrawn) The method according to claim 38 wherein the needle is selected from a 28 gauge, 30 gauge and a 32 gauge needle.
40. (withdrawn) The method according to claim 38 wherein the volumetric flow rate is from about 1 μ L/s to about 4 μ L/s.

41 - 44. (canceled)

45. (withdrawn) The method according to claim 38 further comprising the step of retracting the needle from the skin of the patient following the injection.

46. (canceled)

47. (withdrawn) The method according to claim 46 wherein the device can sequence automatically the inserting of the needle, the injecting of the medicament, and the retracting of the needle.

48. (withdrawn) The method according to claim 46 wherein the volumetric flow rate is from about 0.5 μ L/s to about 20 μ L/s.

49. (previously presented) A device according to claim 1 further comprising a means for attaching the base of the self-contained device for semi-permanent attachment to the skin of the patient, the attaching means being configured wherein during the pumping step, a person is not required to hold the device.

50. (previously presented) A device according to claim 5, further comprising a means for attaching the base of the self-contained device for semi-permanent attachment to the skin of the patient, the attaching means being configured wherein during the pumping step, a person is not required to hold the device.

51. (previously presented) A device according to claim 9, further comprising a means for attaching the base of the self-contained device for semi-permanent attachment to the skin of the patient, the attaching means being configured wherein during the pumping step, a person is not required to hold the device.

52. (previously presented) A device according to claim 15, further comprising a means for attaching the base of the self-contained device for semi-permanent attachment to the skin of the patient, the attaching means being configured wherein during the pumping step, a person is not required to hold the device.

53. (previously presented) A device according to claim 19, further comprising a means for attaching the base of the self-contained device for semi-permanent attachment to the skin of the patient, the attaching means being configured wherein during the pumping step, a person is not required to hold the device.

54. (previously presented) A device according to claim 29, further comprising a means for attaching the base of the self-contained device for semi-permanent attachment to the skin of the patient, the attaching means being configured wherein during the pumping step, a person is not required to hold the device.